State of Tennessee
Health Services and Development Agency
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Public Hearing Questions for

Health Services Development Agency

Created by Section 68-11-1604, *Tennessee Code Annotated*
(Sunset termination June 2017)

1. Provide a brief introduction to the Health Services Development Agency, including information about its purpose, statutory duties, staff, and administrative attachment.

Introduction:

The Tennessee Health Services and Development Agency ["HSDA or Agency"] is an independent body responsible for implementing the certificate of need ["CON"] process, which enables the state to ensure that certain services and health care institutions are developed in a way that ensures access to consumers, protects safety-net providers and results in maximized return for TennCare and other health care expenditures.

The Tennessee Health Services and Planning Act of 2002 (Public Chapter 780, Acts of 2002) authorized its creation. Prior to 2002, the certificate of need program was administered by the Health Facilities Commission. Tennessee first established its certificate of need program in 1973.

The Legislature significantly revised the CON statute, particularly with respect to strengthening conflict-of-interest provisions and discouraging frivolous appeals, to improve the process when replacing the commission with the agency in 2002.

In 2016, the Legislature made significant changes to the CON program to balance the core mission of the CON process with free-market principles. Public Chapter 1043, effective July 1, 2016, eliminated a number of services from review, adds one new service, modified other provisions, and added a fourth criterion for certificate of need — that the proposed health care meets appropriate quality standards. The legislation also directs the agency to work in conjunction with certain departments to develop quality measures and requires it to maintain continuing oversight of all certificates of need approved after July 1, 2016 by requiring applicants to submit annual reports concerning continued need and appropriate quality measures as determined by the agency.

The Agency originally had nine members but now includes eleven members appointed by the Governor and the Speakers, consisting of the following:

- **One person who has recent experience as an executive officer of a hospital or hospital system who may be appointed from lists of qualified persons submitted by interested hospital groups including, but not limited to, the Tennessee Hospital Association;**
- **One representative of the nursing home industry who may be appointed from lists of qualified persons submitted by interested health care groups including, but not limited to, the Tennessee Health Care Association;**
- **One duly licensed physician who may be appointed from lists of qualified persons submitted by interested medical groups including, but not limited to, the Tennessee Medical Association;**
- **One representative of the home care industry who may be appointed from lists of qualified persons submitted by interested home care groups including, but not limited to, the Tennessee Association for Home Care;**
- **One representative of the ambulatory surgical treatment center industry;**
- **A consumer appointed by the Governor;**
- **A consumer appointed by the Speaker of the Senate;**
- **A consumer appointed by the Speaker of the House of Representatives;**
- **The Director of TennCare or designee;**
- **The Comptroller of the Treasury or designee; and**
- **The Commissioner of Commerce and Insurance or designee.**

A certificate of need is required for:

- **The construction, development, or other establishment of any health care institution**
- **Any change in a facility's licensed bed complement, regardless of cost, that (1) increases by one or more the total number of licensed beds greater than 10% during a 3 year period; (2) redistributes beds from acute to long-term care categories; (3) redistributes beds from any category to acute, rehabilitation, child and adolescent psychiatric, or adult psychiatric; or (4) relocates licensed beds to another facility or site;**
- **Initiation of any of the following health care services: burn unit, neonatal intensive care unit, open heart surgery, organ transplantation, cardiac catheterization, linear accelerator, positron emission tomography, home health, hospice, psychiatric, or opiate addiction treatment provided through a nonresidential substitution-based treatment center for opiate addiction;**
- **A change in the location of or the replacement of existing or certified facilities providing health care services and health care institutions, or a change in the location of or the replacement of medical equipment that requires a CON. The relocation of the principal office of a home health agency or hospice within the same county shall not require a certificate of need**
- **Initiation of magnetic resonance imaging: (A) In any county with a population in excess of two hundred fifty thousand (250,000) according to the 2010 federal census or any subsequent federal census, if providing magnetic resonance imaging to pediatric patients; (B) In any county with a population of two hundred fifty thousand (250,000) or less according to the 2010 federal census or any subsequent federal census, for providing magnetic resonance imaging to any patients;**
- **Increasing the number of magnetic resonance imaging machines, in any county with a population of two hundred fifty thousand (250,000) or less according to the 2010 federal census or any subsequent federal census, by one (1) or more, except for replacing or decommissioning an existing machine; and**
- **Establishing a satellite emergency department facility by a hospital at a location other than the hospital's main campus**

Review and consideration of CON applications in Tennessee is a highly participatory, community-driven health planning process - allowing opportunity for public review of applications, public input, and for consideration of applications by the Agency in an open forum. Through this process, input from consumers, community leaders, health care providers, physicians, and others assists the agency in making its determinations.

Applications are considered by the Health Services and Development Agency in a public forum, and are considered upon the following comprehensive criteria:

(1) Whether the project is needed

- **The relationship of the proposal to any existing applicable plans;**
- **The population served by the proposal;**
- **The existing or certified services or institutions in the area;**
- **The reasonableness of the service area;**
- **The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, TennCare participants, and low-income groups;**
- **Comparison of utilization/occupancy trends and services offered by other area providers;**
- **The extent to which Medicare, Medicaid, TennCare, medically indigent, charity care patients and low income patients will be served by the project.**

(2) *Whether the proposal can be economically accomplished and maintained.*

- **Whether adequate funds are available to the applicant to complete the project;**
- **The reasonableness of the proposed project costs;**
- **Anticipated revenue from the proposed project and the impact on existing patient charges;**
- **Participation in state/federal revenue programs;**
- **Alternatives considered; and**
- **The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.**

(3) *The contribution which the proposed project will make to the orderly development of an adequate and effective health care system*.

- **The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);**
- **The positive or negative effects attributed to duplication or competition;**
- **The availability and accessibility of human resources required by the proposal.**

(4) The quality of the project in relation to applicable governmental or professional standards.

Public Chapter 1043 (specifically Section 15) added the previously mentioned fourth criterion. The quality of health care being provided has always been a consideration in certificate of need review but now with the emphasis on continuing need, quality standards, and quality measures, it is a formally elevated consideration.

Purpose:

TCA § 68-11-1603:

> ***It is declared to be the public policy of this state that the establishment and modification of health care institutions, facilities and services shall be accomplished in a manner that is orderly, economical and consistent with the effective development of necessary and adequate means of providing for the health care of the people of Tennessee. To this end, this section shall be equitably applied to all health care entities, regardless of ownership or type, except those owned and operated by the United States government.***

Statutory Duties:

Powers and duties of the agency are defined at TCA § 68-11-1605

In addition to the powers granted elsewhere in this part, the agency has the duty and responsibility to:

(1) Receive and consider applications for certificates of need, to review recommendations on certificates of need, and to grant or deny certificates of need on the basis of the merits of such applications within the context of the local, regional and state health needs and plans, including, but not limited to, the state health plan developed pursuant to § 68-11-1625 in accordance with this part;

(2) Review the state health plan as developed and submitted by the state health planning division and make recommendations to the state health planning division and the governor concerning the state health plan;

(3) Promulgate rules, regulations and procedures deemed necessary by the agency for the fulfillment of its duties and responsibilities under this part, including a procedure for the issuance of a certificate of need upon an emergency application where an unforeseen event necessitates the issuance of a certificate of need to protect the public health, safety and welfare, and where the public health, safety and welfare would be unavoidably jeopardized by compliance with the procedures established under other provisions of this part;

(4) Contract when necessary for the implementation of the certificate of need program as defined by this part; and

(5) Weigh and consider the quality of health care to be provided and the health care needs of consumers, particularly women, racial and ethnic minorities, TennCare or medicaid recipients and low income groups whenever the agency performs its duties or responsibilities assigned by law.

Staff:

The HSDA was staffed at ten positions until July 1, 2016. It abolished two positons as a result of PC 1043.

It had previously been staffed at twelve but because the agency strives to be a good steward of tax dollars, it has abolished two positions in the last six years.

Positions include:

Deputy Director (DD)
Mission critical position

The Deputy Director (DD) is responsible for the day-to-day operation of the CON application review process and is also liaison with the Tennessee Department of Health's Policy, Planning and Assessment Division and State Health Planning Division. The Deputy Director has face-to-face meetings with CON applicants to provide an overview of the CON process and to provide technical assistance when needed. The DD also works closely with the Departments of Health, Mental Health and Substance Abuse Services, and Intellectual and Developmental Disabilities to help each department identify the type of information and analysis needed. In addition to managing the process, supervising the HSD Examiner and the Statistical Analyst, the DD also reviews CON applications and performs summary analysis to help Agency members receive application packets in a timely manner. The DD will oversee the annual reports concerning continuing need and quality measures and any demonstration of compliance that is required per PC 1043.

Administrative Officer (AO)
Mission Critical position

This is a hybrid position responsible for all administrative functions including Human Resources Director, Budget Officer, all other fiscal matters including accounts receivable, accounts payable, travel reimbursement, procurement, inventory, Edison, orientation and training of employees in accordance with applicable laws, rules, regulations, and state policies. Due to cessation of services offered by our valued partner in the Department of Finance and Administration, Shared Services Solutions (SSS), the AO had to assume critical duties related to contracts and coordination of FIA responsibilities. The AO also manages all administrative matters related to monthly board meetings.

General Counsel (GC)
Mission Critical Position

Previously the Agency had two attorneys, one serving as an advisory attorney and the other as a litigating attorney. One of the positions was abolished in FY11/12. This position provides legal opinions and advice in accordance with applicable laws, rules and regulations, and agency policies related to the certificate of need program. The General Counsel also litigates all contested cases. In addition to performing legal duties, legislative analysis, legislative liaison, and public information officer duties are performed.

HSD Examiner
Mission Critical Position

Two examiners were responsible for all aspects of certificate of need application review and analysis for all the different types of health care institutions and health care services; as well as changes in health care institutions related to bed complement. The examiner must understand health planning in general and specifically the State Health Plan; State and Federal health care regulations related both to quality of care and health safety; health care statistics; and health care financing. In addition to review and analysis, the examiner prepares detailed summary reports to be presented to Agency members. Applications are typically in the 200-300 page range with each usually requiring a 2-3 days initial review. Most require 1-3 additional supplemental requests for information before the application can be deemed complete. The summary reports often take several days to prepare as well. When one of the two employees performing these duties retired in 2012, the Agency attempted to operate without filling the second position. The result was that DD was performing reviews and summary analysis almost

exclusively which reduced his efficiency in performing prime duties and responsibilities. Agency staff could not present application packets to Agency members for review in a timely fashion. The second position was filled in the 1st quarter of 2014 which made the workload more manageable. The person filling that position has now retired and plans were underway to bring him back on a part-time basis but the position had to be abolished per PC 1043 due to budget constraints.

Statistical Analyst 3 (SA3)
Mission Critical Position

The Agency has a statutory responsibility to maintain a statewide major medical equipment registry. In addition to registering and describing equipment, equipment owners also file detailed utilization and financial information that is analyzed and then utilized by the HSD Examiner to help the Agency make data driven decisions. In addition to the statutory responsibilities for the medical equipment database, the SA3 had to assume a number of other duties to help the agency better serve its customers including, an "Applicant's Toolbox" section for the website, recording Agency meetings and serving as the contact for any customer needing a CD of an Agency meeting. Additional Duties include CON Progress Reports and Access Database. The SA3 is also the backup OIR Liaison and assists with keeping the website updated. The SA3 will work with the DD to develop a database to track the annual reports concerning continuing need and quality measures and any demonstration of compliance that is required per PC 1043. MRI annual reports, ODC accreditation, 10% increase in beds changes permitted by PC 1043 will also be tracked by the SA3.

Administrative Services Assistant 3 (ASA3)
Mission Critical Position

The ASA 3 is responsible for coordinating all Board-related information monthly. This includes providing administrative support to the Board during each meeting including but not limited to the development of reports, collection of documents, roll call/vote recording, and other related duties. Preparation of post-meeting information including but not limited to notification letters, meeting minutes, certificates, etc. Maintains and creates monthly reports for Agency staff and Board Members, which include Review Cycle, Communique, and Letter of Intent report. The ASA 3 is responsible for the Agency's website and is the OIR Liaison.

Administrative Assistant 1 (AA 1)- abolished due to budgetary constraints per PC1043
Administrative Support for Mission Critical Activities

Two administrative assistants had been responsible for providing support functions for all administrative activities including but not limited to receptionist duties, phones, processing CON applications and other documentation associated with CON applications, fee processing, copying application packets, mail distribution, contested case processing, board packet information, customer service, record retention/scanning, and public records inquiries. Following a review of the business needs of the agency, the AA1 class had been identified for participation in the Voluntary Buyout Program. Due to stream-lined business processes, the agency needed only one AA1 position. One position was vacant and the other employee asked to participate in the VBP so she could retire. The Agency planned to fill the vacant AA1 position after February 2016 when it would have recouped the funds from the VBP. However, the position had to be abolished per PC 1043 due to budget constraints.

Executive Administrative Assistant 2 (EAA2)
Administrative Support for Mission Critical Activities

This was a newly established position reclassified from an Administrative Assistant 1 position as a result of the Voluntary Buyout Program. This position was established to work primarily with the Executive Director and General Counsel who have never had administrative support. Now the employee is providing all administrative support activities for the entire program due to the abolishment of the AA1 position.

Executive Director (ED)
Mission Critical Activities

The executive director's duties are delineated at TCA § 68-11-1606. The executive director is the chief administrative officer of the agency and the appointing authority and serves at the pleasure of the agency.

The Agency is now down to only *eight* staff members. With such a small staff, it is necessary that each team member be capable of wearing many hats. This small group has many complementary skills. The HSD Examiner has extensive knowledge in the mental health field (clinical, business, and regulatory), managed care organizations, and in fraud investigations (certified fraud examiner); the former HSD Examiner had extensive experience in health care administration, physician practice management, and public health administration. The agency had hoped to retain that by bringing the employee back on a part-time basis and to also utilize that experience to help start the quality measures program. But that is no longer possible due to budgetary constraints. The DD has extensive experience in health planning and data. In addition to many years' experience leading the certificate of need program, the executive director has a background in public health including extensive knowledge regarding state and federal regulatory requirements for health care facilities. The SA3 manages the statutorily required medical equipment registry, provides important statistical information for the CON review process, and manages the statutorily required progress reports. The ASA 3 manages all the pre- and post-board meeting information each month in addition to being the OIR liaison. The General Counsel advises staff throughout the review process, provides advice to the executive director and board members, litigates contested cases, and performs various other vital duties. The AO manages Human Resource and Fiscal needs in addition to managing all other administrative functions for agency members and staff. The EAA 2 provides front-line customer service including escorting guests in and out of the building, handling public record requests, telephone inquiries, and all other activities related to the processing of CON applications and support activities.

Section 16 of Public Chapter 1043 directs Agency to maintain continuing oversight of certificates of need approved after July 1, 2016 by requiring applicants to submit annual reports concerning continued need and appropriate quality measures as determined by the agency. At the current time, one of the agency's greatest concerns is the long-term staffing for the quality measures/continuing need requirement.

Administrative Attachment:

The HSDA is an independent body under the Agencies, Boards and Commissions Section of the Executive Branch. It is not administratively attached to any department. The agency works closely with the Tennessee Departments of Health, Mental Health and Substance Abuse Services, and/or Intellectual and Developmental Disabilities for review of certificate of need applications whose subject matter or funding is within their respective jurisdictions.

2. Provide a list of current members of the agency and describe how membership complies with Section 68-11-1604, *Tennessee Code Annotated*. Are there any vacancies? If so, what steps have been taken to fill the vacancies?

Please see the following page. Currently, there is one vacancy, to be filled by the speaker of the house. The three consumer members are statutorily fixed and other non-government members are representatives of five constituent industries. Two female designees serve (one serving for a female member; one serving for a male member). At the current time, there are no racial minorities. Two members were at least 60 years of age or older at the time of appointment. Three members are from East Tennessee, six from Middle including the three state designees, and one from West Tennessee.

HEALTH SERVICES AND DEVELOPMENT AGENCY

	Robert S. Doolittle Represents: **Consumers** **(Governor)** Term Expiration: 6/30/2017
Martin D. Fleming, M.D., FACS Represents: **Physicians** Term Expiration: 6/30/2017	**Joe Grandy** Represents: **Consumers** (Speaker of the Senate) Term Expiration: 6/30/2018
Thom Mills Represents: **Home Care** Term Expiration: 6/30/2018	**VACANT** Represents: **Consumers** (Speaker of the House) Term Expiration: 6/30/19
Todd Taylor Represents: **Nursing Homes** Term Expiration: 6/30/2019	**Lisa Jordan** **Assistant Commissioner** **TennCare Oversight Division** designee for Commissioner of Commerce & Insurance Julie Mix McPeak
Corey Ridgway Represents: **Ambulatory Surgical Treatment Centers** Term Expiration: 6/30/2019	**Jaclyn Harding** **Administrative Systems Coordinator** designee for Comptroller of the Treasury Justin Wilson
Paul Korth Represents: **Hospitals** Term Expiration: 6/30/2019	**Keith Gaither** **Director of Managed Care Operations** designee for Director of TennCare Wendy Long, M.D.

3. Does the agency's membership include public/citizen members? Female members? Members of a racial minority? Members who are 60 years of age or older at the time of appointment?

The three consumer members are statutorily fixed and other non-government members are representatives of five constituent industries. There are currently two female designees serving (one serving for a female member; one serving for a male member). At the current time, there are no racial minorities. Two members were at least 60 years of age or older at the time of appointment.

4. How many times did the agency meet in fiscal years 2015 and 2016? How many members were present at each meeting?

FY 14/15	
Month/Year	**Members Present**
07/14	**9**
08/14	**8**
09/14	**9**
10/14	**9**
11/14	**9**
12/14	**10**
01/15	**(No Mtg.)**
02/15	**9**
03/15	**11**
04/15	**(No Mtg.)**
05/15	**11**
06/15	**8**

FY15/16	
Month/Year	**Members Present**
07/15	**(No Mtg.)**
08/15	**10**
09/15	**9**
10/15	**10**
11/15	**10**
12/15	**10**
01/16	**11**
02/16	**11**
03/16	**9**
04l/16	**9**
05/16	**10**
06/16	**10**

5. What per diem or travel reimbursement do members receive? How much was paid to agency members during fiscal years 2015 and 2016?

All members, with the exception of state members, receive $50.00 per Diem per day per TCA § 68 -11-1604 (d) (1) and are reimbursed for all travel and other necessary expenses per State Travel Regulations.

FY/15: $17,166

FY/16: $23,823

6. What were the agency's revenues (by source) and expenditures (by object) for fiscal years 2015 and 2016?

Source	FY	Revenue	Expenditure
254	15	$ 839,233.26	$ 1,062,300
880	15	$ 11,760.00	
254	16	$ 955,656.96	$ 1,062,081
880	16	684.20	

Does the agency carry a reserve fund balance and, if so, what is the total of that reserve fund balance?

The Agency does not have a reserve fund. Effective July 1, 2016, an amount not to exceed $300,000 was appropriated by the General Assembly in Public Chapter 758 (General Appropriations Act) as a carry forward. These funds had previously been carried forward annually for audit costs.

From 2002 to 2008, the Agency was permitted to carry a reserve fund balance. The Agency was self-supported by the collection of application fees. Fees ranged from $3,000 to $45,000 per application based on project cost ($2.25 per $1,000 project cost). Collections exceeded expenditures and excess revenue transferred to the reserve fund. Applications ranged from 100 to 120 per year. Many older health care facilities were being replaced (Hill-Burton era) during this period which accounts for what may seem to be excessive fees.

Public Chapter 1120, Acts of 2008 effectively changed how the agency was funded. It made general appropriations for the HSDA budget going forward, transferred its fees to the General Fund, and transferred the reserve balance of approximately $1.5 million ($1,538,976.38) to the General Fund. This was the beginning of the economic crisis in 2008.

Certificate of need applications have dropped in half since that time, ranging between 52 to a high of 67 last year. A further drop in CON applications is expected due to passage of Public Chapter 1043, especially the applications that generated the higher applications fees because a certificate of need is no longer required to modify a health care facility.

It is important to note after Public Chapter 1120, Acts of 2008 changed the funding of the Agency from fee-funding to an appropriation from the General Fund, the Agency always came in under budget and more often than not, reverted funds to the General Fund, even in the years a reversion target was not identified, in addition to the fees it collected. During the time the Agency was funded via an appropriation from the General Fund, over 6.75 million dollars in fees were deposited to the General Fund.

Public Chapter 1043 changed the funding mechanism once again back to a fee-funding mechanism; however, most of the applications that would have generated higher fees have been eliminated (primarily, modification of health care institutions). Even with the fee increase, it is unlikely that there will ever be any excess revenue to revert to a reserve fund.

7. Is the agency subject to Sunshine law requirements (Section 8-44-101 et seq., Tennessee Code Annotated) for public notice of meetings, prompt and full recording of minutes, and public access to minutes? If so, what procedures does the agency have for informing the public of its meetings and making its minutes available to the public?

The Agency is subject to Sunshine law requirements. Meeting notices are posted on the www.tn.gov website, agency's website and also in Legislative Plaza and other state buildings. The Agency's Notice of Review and Communique are also posted, with descriptions of projects to be reviewed. Minutes are prepared and adopted for every meeting, posted on the website and are available in the Agency's office for public review. Transcripts and audio recordings of the Agency's meetings are also available in the Agency's office for public review.

8. What policies or procedures does the agency have in place to address potential conflicts of interest by agency members, staff, and employees?

The governing statute has comprehensive conflict of interest restrictions, restated in the agency's rules for emphasis, which have served the agency well since its inception in 2002. Agency members and staff are required to read and execute conflict of interest forms annually that both inform of the policies and request disclosures of potential conflicts of interest. Agency members routinely recuse themselves from participation when there is a potential conflict of interest. The Deputy Director will review a certificate of need application if a conflict exists for review staff.

9. Has the agency promulgated rules as authorized in Section 68-11-1605(3), *Tennessee Code Annotated?*

Rules were promulgated in 2005 and are being updated now to comply with the changes brought about by PC 1043.

10. Please describe the agency's activities during fiscal years 2015 and 2016 to fulfill each of the duties outlined in Section 68-11-1605(1) through (5) and 1606 (c) and (d), *Tennessee Code Annotated.*

TCA Section 68-11-1605(1) requires the Agency to "receive and consider applications for certificates of need, to review recommendations thereon, and to grant or deny certificates of need on the basis of the merits of such applications within the context of the local, regional and state health needs and plans, including, but not limited to, the state health plan developed pursuant to § 68-11-1625, in accordance with the provisions of this part". Those are the Agency's very fundamental activities, and the Agency has historically had a public meeting almost every month at which it considered CON applications as directed by law.

However, the State Health Planning Division of the Department of Finance and Administration, which is administratively attached to the Department of Health, is charged by law with developing a comprehensive state health plan, and is in the process of doing so. The Agency uses "*Tennessee's Health: Guidelines for Growth*" ["*Guidelines*"], as modified periodically in the state health plan to guide certificate of need decisions. The State Health Planning Division is currently working on a 6th edition of the health plan now.

TCA Section 68-11-1605(2) requires the Agency to "review the state health plan as developed and submitted by the state health planning division and make recommendations to the state health planning division and the governor concerning the state health plan;". The Agency regularly follows developments in the process of developing the state health plan and revisions of the *Guidelines*. Agency members and staff have had much input in the process, and have received regular updates from the State Health Planning Division at Agency meetings. The Agency's executive director is a member of the State Health Planning Division's advisory board. Agency staff regularly participates in meetings in with Health Planning staff and share data and information.

TCA Section 68-11-1605(3) requires the Agency to "promulgate rules, regulations and procedures deemed necessary by the agency for the fulfillment of its duties and responsibilities under this part, including a procedure for the issuance of a certificate of need upon an emergency application where an unforeseen event necessitates the issuance of a certificate of need to protect the public health, safety and welfare, and where the public health, safety and welfare would be unavoidably jeopardized by compliance with the procedures established under other provisions of this part". The Agency first promulgated rules, which took effect in November 2005. The rulemaking process was open and input was solicited from interested parties in the drafting and discussion of the rules by Agency staff and members. The Agency promulgated emergency rules to address Section 20 of PC 1043 which took effect July 1, 2016 and then addressed a comprehensive update to the rules at the August 2016 Agency meeting.

TCA Section 68-11-1605(4) requires the Agency to "contract when necessary for the implementation of the certificate of need program as defined by this part". The Agency does not contract for the implementation of the certificate of need program. The Agency has only one contract and it is explained in the response to Question 31.

TCA Section 68-11-1605(5) requires the Agency to "weigh and consider the quality of health care to be provided and the health care needs of consumers, particularly women, racial and ethnic minorities, TennCare or medicaid recipients and low income groups whenever the agency performs its duties or responsibilities assigned by law". Applicants must address these concerns in the application for CON. The needs of consumers, particularly women, racial and ethnic minorities, TennCare or Medicaid recipients and low income groups are always considered by the Agency when making decisions about whether to approve or deny CON applications, which forces applicants to address projects' impact upon such citizens, knowing throughout the application process that such concerns will be weighed in the decision-making process. Their needs are also paramount when Agency members and staff engage in the health planning process. Quality health care has also been of paramount importance and it has been codified in the statute now as a result of PC 1043, effective July 1, 2016.

TCA Section 68-11-1606(c) (1) requires the executive director to "keep a written record of all proceedings and transactions of the agency, which shall be open to public inspection during regular office hours". Transcripts and recordings of Agency meetings, application files, staff determinations, and other documents are kept in the Agency's office. Agency records are available for public inspection during regular office hours.

TCA Section 68-11-1606(c) (2) requires the executive director to "administer the certificate of need process". The executive director does so by overseeing the receipt and review of CON applications; submission of applications for department review; distribution of applications, agendas and other information to agency members; logistics of Agency meetings; provision of notice to the public; maintenance of the Agency's website with information of use to the public; overseeing agency staff; Agency finances; issuance of staff determinations; conduct of contested cases; rulemaking; public records requests; other duties related to the CON program; and by communicating with Legislators, Agency members, other state agencies, press, affected constituencies and the general public.

TCA Section 68-11-1606(c) (3) requires the executive director to "represent the agency before the general assembly". The executive director does so, as well as Agency staff at her direction.

TCA Section 68-11-1606(c) (4) requires the executive director to "oversee the issuance of responses to requests for determination regarding the applicability of the provisions of this

part". The executive director oversees the issuance of staff determinations by Agency counsel.

TCA Section 68-11-1606(c) (5) requires the executive director to "prepare the agenda, including consent and emergency calendars, and notice to the general public of all meetings and public hearings of the agency". The executive director does so, as well as Agency staff at her direction.

TCA Section 68-11-1606(c) (6) requires the executive director to "employ such personnel, within the budget, to assist in carrying out the provisions of this part". The executive director employs the above-referenced staff to assist in carrying out the provisions of this part.

TCA Section 68-11-1606(c) (7) requires the executive director to "carry out all policies, rules and regulations that are adopted by the agency and supervise the expenditure of funds. The executive director does so.

TCA Section 68-11-1606 (d) provides the Agency the authority to delegate certain duties which is within is discretion including (1) Granting approval, denial, deferral or referral to the agency of applications for certificate of need in accordance with § 68-11-1609; and (2) Granting approval or denial of modifications, changes of conditions or ownership, and extensions of certificates of need in accordance with this part. The Agency has granted the authority to defer, modify, approve a change of condition or ownership, and extension but has not granted the authority to approve or deny CON applications since the State Health Plan is not yet totally complete with updated criteria and standards.

11. Public Chapter 1043 made various changes to provisions pertaining to the administration of the Certificate of Need (CON) process. How has the agency revised its operations to comply with this public chapter?

Public Chapter 1043 made significant changes to the CON program; the Agency and its staff are working to implement the changes as directed, and to make the transition to the new process as smooth as possible for the applicants. 1) The certificate of need application form has been revised to be consistent with the changes in the statute. 2) All CON-related correspondence has been revised to notify applicants of the significant changes, especially related to continuing need, quality standards, quality measures, and annual reports. 3) Other reporting forms have been altered to reflect the recent statutory changes including the Intent to Alter Bed Capacity as it relates to the ability to now increase hospital, rehab, or mental health beds by 10% or less every 3 years without a CON.

Public Chapter 1043 directs the Agency to enact rules detailing applicable quality measures to ensure that only services meeting applicable quality standards are approved. Agency staff conducted research and met with representatives of the Departments of Health, Mental Health and Substance Abuse Services, and Intellectual and Developmental Disabilities. Agency staff is working on drafting quality measures and will circulate to providers and other stakeholders and the aforementioned state departments before proposing to the Agency for rulemaking. <u>The Department of Intellectual and Developmental Disabilities was asked to participate in the discussion even though they were not included in the legislation since they are a reviewing agency for certificate of need applications.</u>

Public Chapter 1043 has necessitated changes to the Agency's rules. Many such changes are matters of housekeeping to ensure the rules reflect what was added and what was subtracted by the new law. Emergency Rulemaking was necessitated by Public Chapter 1043's elimination of one-half of the Agency's revenue stream, while mandating that the Agency adjust its fees to cover the shortfall (on fewer applications, particularly high dollar applications). While not wanting to raise fees, the Agency followed the law and did so, while

expressing the hope that the budget could be fixed to enable them to be lowered in the future. Prior to raising fees, the Agency reviewed the cost-cutting measures recommended by the executive director which included a 20% reduction in staff and 50% reduction in Agency meetings, as well as other cost-cutting measures.
Public Chapter 1043 has only been law since July 1, 2016. As the Agency and its staff administer the reformed CON program, every effort will be made to make necessary adjustments to the process and budget as the full effect of the changes takes place over time. The Agency and its staff are making every effort to make the transition as smooth as possible for applicants.

12. Describe any items related to the agency that require legislative attention and your proposed legislative changes.

Public Chapter 1043 eliminated one-half of the Agency's revenue stream, while eliminating far less than half of the Agency's workload; this is because 1) far less than half of CON applications were eliminated; 2) applications bringing the high, maximum fees were almost entirely eliminated, while applications bringing the low, minimum fees mostly remain; 3) General appropriation funding from the General Fund was eliminated; and 4) additional duties were mandated without additional funding. In order to make the bill revenue-neutral, the Agency was directed by Public Chapter 1043 to "adjust" its fees to cover the eliminated revenue. The Agency now receives almost every dollar from application fees, which means they had to be raised significantly to comply with Public Chapter 1043; particularly since half of remaining applications are expected to be what have been $3,000 "minimum fee' applications, while most applications of $45,000 that covered so much of the Agency's budget were eliminated.

Agency members did not take this lightly, and ran different numbers and scenarios at its public meeting in June 2016, before arriving at numbers that would ensure its ability to meet its budget (after staff reductions and other cost-cutting measures) – even during lean years (applications and fees vary widely from month-to-month, and year-to year). While the Agency has eliminated 1/5 of its staff to save costs, it is down to only 8 employees, leaving little cost-savings left to be had while fulfilling core functions.

Public Chapter 1043 took effect 7/1/16, and had no provision allowing for the Agency to wait 1-2 years before "adjusting" (i.e., significantly raising) fees to become self-sufficient. Agency staff consulted with State Budget staff several times to discuss the HSDA budget situation. Agency staff understood that its budget would be revisited after several months and adjusted downward based upon annualizing revenue received with fewer applications, particularly fewer "maximum fee" applications. This left The Agency and its staff little time to make hard choices concerning cost-cutting measures and significantly raising fees. Budget Staff agreed that Emergency Rulemaking must be done in order to adjust the fee schedule.

The Agency implores the legislature to fix the budget situation created by Public Chapter 1043, to enable it to meet its budget while lowering fees for applicants.

13. Should this agency be continued? To what extent and in what ways would the absence of the agency affect the public health, safety, or welfare?

The State of Tennessee spends a significant portion of its budget on health and social services, and therefore, has a vested interest in ensuring that health care dollars maximize results for consumers and preserves the backbone of the public health system. The HSDA plays a critical role in providing access to quality health care while containing health care costs through the certificate of need ["CON"] program.

There is no evidence that elimination of certificate of need reduces costs per service. Health care is not as subject to general economic principles as other sectors of the economy because it is usually something the buyer has to have, rather than something it chooses to have, the seller is often the health care provider on whose advice the buyer relies to make decisions, and third-party insurance (government, private) usually pays most of the direct bill.

There is evidence that elimination of CON results in increased utilization of expensive services without better outcomes for patients. Elimination of the CON program would result in increased expenditures by TennCare, private payors, employers and consumers. In fact, Fiscal Review's fiscal note on what became Public Chapter 1043 noted an assumed one percent increase in TennCare costs and at least a two percent increase in costs to the state sponsored health plans.

In 2016, the legislature passed reforms to the state's CON laws that have significantly reduced the amount of regulation while leaving much of the provisions in place that protect struggling full-service providers in rural areas from unnecessary competition (not all competition) that would render them unable to continue providing care to the TennCare, Medicare and indigent populations, would leave them unable to continue providing necessary services that aren't profitable, and in some cases, would threaten the very existence of the sole hospitals for wide rural areas of the state.

It would only make sense to let the recently enacted reforms to the CON program play out before considering further changes.

Has the agency developed and implemented quantitative performance measures for ensuring it is meeting its goals? If the agency has developed and implemented quantitative performance measures, please answer questions 15 through 22. If the agency has not developed quantitative performance measures, proceed to question 23.

Yes. Please see responses to questions 14-21 to see how the Agency is currently performing performance measurements.

In addition to continuing to measure items related to the medical equipment registry, Public Chapter 1043 charges the Agency with the development of measures for assessing continuing need and quality of entities receiving certificates of need on or after July 1, 2016. Agency staff conducted research and met with representatives of the Departments of Health, Mental Health and Substance Abuse Services, and Intellectual and Developmental Disabilities. The initial meeting was held on August 18, 2016 with representatives from the Departments of Health, Mental Health and Substance Abuse Services and Intellectual and Developmental Disabilities. Executive Director Hill provided an update to the Agency on August 24, 2016 and presented the information to the Board for Licensing Health Care Facilities on September 7. Stakeholder input will be sought before the Agency initiates rulemaking. Certificate of need holders are required to submit annual reports on all CONs issued after July 1, 2016 regarding continuing need and quality measurements. Performance measurements will be developed.

14. What are your key performance measures for ensuring the agency is meeting its goals? Describe so that someone unfamiliar with the program can understand what you are trying to measure and why it is important to the operation of your program.

Tennessee law requires the Agency maintain a registry of major medical equipment which should include CT scanners, Linear Accelerators, Lithotripters, MRI's, and PET scanners. The registry contains not only the location of these units but also the general information

about them (brand name and type) and their yearly utilization (number of procedures). The Agency tracks the number of submitted registrations and submitted utilizations received prior to June 30th. Completion benchmark goals were developed for each type of report

15. What aspect[s] of the program are you measuring?

The Agency is measuring how many registrations and how many utilization reports are submitted in comparison to how many providers there are in the state. Percentage completion goals have been adjusted as needed.

16. Who collects relevant data and how is this data collected (e.g., what types information systems and/or software programs are used) and how often is the data collected? List the specific resources (e.g., report, other document, database, customer survey) of the raw data used for the performance measure.

Every January, updated registrations and the previous calendar year's utilizations are submitted for each provider who utilizes one or more of these units. As the reports are submitted, they are logged, checked for tabulation accuracy, and entered into the database by the Statistical Analyst III. The data is used to help determine where exactly units are located and how many procedures they handle. The information within the registry is used to help develop a visual on the imaging activity by county within the state. It also assists local providers in complying with the Affordable Care Act's provision to supply patients with a list of local imaging providers to help in patient care decisions.

17. How is the actual performance measure calculated? If a specific mathematical formula is used, provide it. If possible, provide the calculations and supporting documentation detailing your process for arriving at the actual performance measure.

The goal, percent, is calculated by tallying the number of received reports and dividing by the total number of providers (potential reports). That number is then converted to a percent.

18. Is the reported performance measure result a real number or an estimate? If an estimate, explain why it is necessary to use an estimate. If an estimate, is the performance measure result recalculated, revised, and formally reported once the data for an actual calculation is available?

The result is a real number percent of what was received.

19. Who reviews the performance measures and associated data/calculations? Describe any process to verify that the measure and calculations are appropriate and accurate.

Performance measures are reviewed by the Agency executive management. Statistical Analyst III verifies the statistics submitted by the equipment owners/providers.

20. Are there written procedures related to collecting the data or calculating and reviewing/verifying the performance measure? Provide copies of any procedures.

Written procedures have been developed that describes a step by step process of collecting, tracking, and entering the reports for the Medical Equipment Registry. These procedures include guidance on how to locate potential submitted or entered errors.

21. Describe any concerns about the agency's performance measures and any changes or improvements you think need to be made in the process.

The rate of medical equipment registry and utilization report completion is constantly over 95%. Statistical Analyst III is constantly recognizing any reporting abnormalities and is able to resolve these issues with the medical equipment owners/providers

22. Please list all agency programs or activities that receive federal financial assistance and, therefore are required to comply with Title VI of the Civil Rights Act of 1964. Include the amount of federal funding received by program/activity.

None, since the Agency does not receive federal funds, per Attorney General Opinion Number 04-130.

If the agency <u>does</u> receive federal assistance, please answer questions 24 through 31. If the agency <u>does not</u> receive federal assistance, proceed directly to question 30.

23. Does your agency prepare a Title VI plan? If yes, please provide a copy of the most recent plan**. Not applicable**

Does your agency have a Title VI coordinator? If yes, please provide the Title VI coordinator's name and phone number and a brief description of his/her duties. If not, provide the name and phone number of the person responsible for dealing with Title VI issues. **Not applicable**

24. To which state or federal agency (if any) does your agency report concerning Title VI? Please describe the information your agency submits to the state or federal government and/or provide a copy of the most recent report submitted. **Not applicable**

25. Describe your agency's actions to ensure that agency staff and clients/program participants understand the requirements of Title VI. **Not applicable**

26. Describe your agency's actions to ensure it is meeting Title VI requirements. Specifically, describe any agency monitoring or tracking activities related to Title VI, and how frequently these activities occur. **Not applicable**

27. Please describe the agency's procedures for handling Title VI complaints. Has your agency received any Title VI-related complaints during the past two years? If yes, please describe each complaint, how each complaint was investigated, and how each complaint was resolved (or, if not yet resolved, the complaint's current status). **Not applicable**

28. Please provide a breakdown of current agency staff by title, ethnicity, and gender.

Title	Ethnicity	Gender
Executive Director	**W**	**F**
Deputy Director	**W**	**M**
General Counsel	**W**	**M**
HSD Examiner	**W**	**M**
Administrative Officer	**W**	**F**
Statistical Analyst	**W**	**F**
ASA III	**W**	**M**
Executive Adm. Assistant	**W**	**F**

29. Please list all agency contracts, detailing each contractor, the services provided, the amount of the contract, and the ethnicity of the contractor/business owner.

The HSDA has only one contract in the amount of $15,000 for court reporting services with Ace Court Reporting Services for the period July 1, 2016-June 30, 2017. The ethnicity is white.